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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,971	07/07/2000	STEPHEN ROY PENNINGTON	60319-010	4635

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EXAMINER

WESSENDORF, TERESA D

ART UNIT PAPER NUMBER

1639

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/582,971

Applicant(s)

PENNINGTON, STEPHEN ROY

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9, 17-21, 28-31 and 37-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 17-21, 28-31 and 37-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/10/06 has been entered.

***Status of Claims***

Claims 1-9, 17-21, 28-31 and 37-46 are pending and under examination.

***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 17-21, 28-31 and 37-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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A). Claim 1 is unclear as to what is actually being claimed. It appears incomplete for omitting essential and cooperative relationships of elements and steps. The omissions amount to a gap or lack of nexus in the method steps. For example, it is unclear as to the essentiality of step (A) i and ii of subjecting or predicting the target protein by its mass spectrometry determination and how it correlates to its antibody generation of step (B). Furthermore, the expression "mass spectrometry based characterization is confusing as to its exact meaning". Is the intent to characterize the target protein by its mass spectrometry? Is the known data, the data of the target protein, if so then the step of "predicting" appears inappropriate. The use of the phrase "and/or" in step (B)i and ii is confusing. When the alternative "or" step is used, then step ii reference to "said at least one antibody" lacks antecedent basis of support from the preceding steps. It appears more appropriate that the two steps are connected to each other or step (B) ii is reacted with the target protein and selecting the antibody that binds to the target protein. In case (B)ii, step (C) would not be necessary since step (B) ii is a screening process. Step (C) would appear more appropriate for step (B)i. The phrase "each antibody being used individually" in step (C) is ambiguous as to its meaning within the context of the claim.

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Step (C) ii is confusing as to the eluting process. In step (D) is the target protein bound to the antibody or the target protein eluted without the antibody, if so how could step (E) identify the antibody from the eluted unbound, target protein? [The numerous amendments to the claims do not make sense.]

B). In claims 1, 2, 4 and 5, it is unclear whether the "target protein of interest" is different from the target protein recited in the body of the claims. The inconsistent use of terminologies provide for confusion and ambiguity. See also claims 28 and 29. "Plurality" and "mixtures" of proteins are relative terms and confusing when used in the claimed context of at least one target protein.

C). Claim 6 is unclear as to the step of "acquisition of sequence tag data" especially in view of the basis of mass spectrometry **based** characterization.

D). Claim 30 "the other mass spectrometry" lacks antecedent basis of support from the base claim.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 17 and 28-29 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Nelson et al (US 2001/0019829).

Nelson discloses at [0149] a method of determining the presence of one or more specific antibodies in sera. The method involves retrieval of a portion of the general antibody population present in a sample, and use of this portion to construct the affinity reagent. The affinity reagent is then screened with specific antigens. Antigens are retained by the

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affinity reagent if the specific antibody is present in the original sample, and will register in the mass spectrum (indicating the presence of the specific antibody). Nelson discloses at [0150] that the specimen was that of blood serum drawn from a rabbit immunized against the toxin, alpha-cobratoxin. The affinity reagent was prepared by mixing of protein A supported on 6% agarose beads with a solution containing the serum and incubated for two hours (gentle agitation at room temperature). At [0151] preparation containing multiple antigen species was prepared and MALDI mass spectrometrically analyzed. The resulting mass spectrum in FIG. 13 shows multiple signals corresponding to multiple antigens in the preparation. At [0152] it is disclosed that the affinity reagent was then incubated with the preparation following similar mass spectrometric immunoassay protocols already described to see which of the antigen species from the preparation of screening antigens were retained. The resulting mass spectrum is shown in FIG. 14. A signal at the mass-to-charge ratio of alpha-cobratoxin indicates the retention of alpha.-cobratoxin by the affinity reagent, which in turn indicates the presence of anti-.alpha.-cobratoxin present in the serum from which the affinity reagent was made. Accordingly, the method of Nelson anticipates or renders obvious the claimed method. [MPEP 2116.01 states that the

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rejection under 102/103 is proper since the claim is confusing and subject to numerous interpretations].

Claims 1-9, 17-21, 28-31 and 37-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson in view of Xu (2003/0157089) and Zsebo et al (6,759,215).

Nelson does not disclose a sequence tag data. However, Xu discloses at [0823] that it is possible to obtain a full length cDNA sequence by analysis of sequences provided in an expressed sequence tag database, such as that available from GenBank. Searches for overlapping ESTs may generally be performed using well-known programs (e.g., NCBI BLAST searches), and such ESTs may be used to generate a contiguous full-length sequence. Full-length DNA sequences may also be obtained by analysis of genomic fragments. Xu discloses at [0946] that the assay is performed in a flow-through or strip test format, wherein the binding agent is immobilized on a membrane, such as nitrocellulose. In the flow-through test, polypeptides within the sample bind to the immobilized binding agent as the sample passes through the membrane. [0958] discloses Rosettesep that is used to enrich cells directly from a blood sample and consists of a cocktail of tetrameric antibodies that target a variety of unwanted cells and crosslinks them to glycophorin A on red blood cells (RBC)



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present in the sample, forming rosettes. It is then centrifuged over ficoll. Zsebo discloses at Example 2, the use of formic as eluting agent. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ nitrocellulose or Ficoll or formic in the method of Nelson since these reagents are conventionally employed in mass spectrometry as taught by Xu and Zsebo. One would have been motivated to use this material depending upon the desirability or advantageous effect it has on the components under analysis.

#### ***Response to Arguments***

Applicant states that although not explicitly recited in the claims, applicant suggests that the present invention provides a method of creating an experimental tool wherein protein affinity ligands are identified and screened for through the use of comparative mass spectrometry based characterizations as demonstrated in step (e) of amended claim 1.

In reply, applicant remarks do not aid in clarifying the method steps of the claims. Applicant's remarks do not seem to correlate with what is being claimed.

#### ***Conclusion***

Hutchens et al discloses mass spectrometry analysis of antibody and target protein.

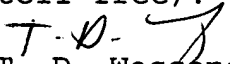
No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
T. D. Wessendorf  
Primary Examiner  
Art Unit 1639

tdw  
April 25, 2006